

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Karl Emil Groth et al.

Attorney Docket: FCM1005USC2

Serial No.: 10/667,917

Group Art Unit: 3738

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Filed: September 22, 2003

Examiner: Thomas C. Barrett

JAN 25 2005

For: TREATMENT OF HEPATITIS C USING HYPERTHERMIA**INFORMATION DISCLOSURE STATEMENT**Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to Sections 1.56, 1.97, and 1.98 of Title 37 of the Code of Federal Regulations, the following information is set forth in compliance with Applicants' duty of disclosure, as well as the duty of others substantively involved in the preparation of the above-titled application.

The Applicants and others substantively involved in the preparation of the application are aware of the documents listed on the enclosed PTO-1449 form. All of the listed documents were submitted or cited in parent application Serial No. 09/484,360, filed January 14, 2000, except for U.S. Patent Nos. 6,347,633 and 6,644,320, which are issued patents in the same family as this application.

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**Certification of Facsimile Transmission**

I hereby certify that 8 pages including cover are being facsimile transmitted to the Patent and Trademark Office on the date shown below:

Date:

January 25, 2005

Signature:

Jodi JungName: Jodi Jung

Information Disclosure Statement  
Applicants: Karl Emil Groth et al.  
Serial Number: 10/667,917

Attorney Docket: FCM1005USC2

The present statement reflects the direct knowledge of the undersigned and information disclosed to the undersigned by the Applicants and others substantively involved in the preparation of the present application pursuant to their duty under 37 C.F.R. § 1.56.

Applicants reserve the right to show, pursuant to 37 C.F.R. § 1.131 or otherwise, that any one or more of the documents listed on the PTO-1449 form is not prior art to the present invention.

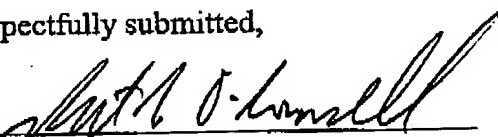
Pursuant to the Manual of Patent Examining Procedure, Chapter 609, Applicants request that the Examiner consider each of the listed documents and initial and return to the undersigned a copy of the enclosed PTO-1449 form.

It is believed that no fees are due in connection with this submission. However if this is incorrect, please charge any fees to Deposit Account No. 16-2312.

Respectfully submitted,

Date: January 25, 2005

By

  
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| FORM PTO-1449<br><br>U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE<br><br>INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT<br><br>(Use several sheets if necessary) | ATTY. DOCKET NO.   | SERIAL NO. |
|  | FCM1005USC2        | 10/667,917 |
|  | APPLICANTS         |            |
|  | Karl Groth et al.  |            |
|  | FILING DATE        | GROUP      |
|  | September 22, 2003 | 3738       |

## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL | DOCUMENT NUMBER |   |   |   |   |   |   | DATE     | NAME         | CLASS | SUBCLASS | FILING DATE IF<br>APPROPRIATE |
|---------------------|-----------------|---|---|---|---|---|---|----------|--------------|-------|----------|-------------------------------|
|                     | 4               | 2 | 9 | 8 | 0 | 0 | 6 | 11/03/81 | Parks        |       |          |                               |
|                     | 5               | 3 | 9 | 1 | 1 | 4 | 2 | 02/21/95 | Sites et al. |       |          |                               |
|                     | 5               | 4 | 8 | 6 | 2 | 0 | 8 | 01/23/96 | Ginsburg     |       |          |                               |
|                     | 5               | 6 | 7 | 4 | 1 | 9 | 0 | 10/07/97 | Kelly        |       |          |                               |
|                     | 5               | 7 | 3 | 0 | 7 | 2 | 0 | 03/24/98 | Sites et al. |       |          |                               |
|                     | 6               | 1 | 7 | 2 | 0 | 4 | 6 | 01/09/01 | Albrecht     |       |          |                               |
|                     | 6               | 3 | 4 | 7 | 6 | 3 | 3 | 02/19/02 | Groth et al. |       |          |                               |
|                     | 6               | 6 | 4 | 4 | 3 | 2 | 0 | 11/11/03 | Groth et al. |       |          |                               |
|                     |                 |   |   |   |   |   |   |          |              |       |          |                               |

## FOREIGN PATENT DOCUMENTS

|  | DOCUMENT NUMBER  | DATE     | COUNTRY | CLASS | SUBCLASS | TRANSLATION |    |
|--|------------------|----------|---------|-------|----------|-------------|----|
|  |                  |          |         |       |          | YES         | NO |
|  | DE 195 31 935 A1 | 02/20/97 | Germany |       |          |             |    |
|  |                  |          |         |       |          |             |    |
|  |                  |          |         |       |          |             |    |
|  |                  |          |         |       |          |             |    |
|  |                  |          |         |       |          |             |    |
|  |                  |          |         |       |          |             |    |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

|  |   |
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|  | Alonso et al., "Whole-Body Hyperthermia and the Augmentation of Cellular Cytotoxic Responses in the Treatment of Acquired Immune Deficiency Syndrome," <u>Southern Medical Journal</u> , 88(10):S142 (1995).                                |
|  | Alonso et al., "Systemic Hyperthermia in the Treatment of HIV-related Disseminated Kaposi's Sarcoma," <u>Am. J. Clin. Oncol. (CCT)</u> , 17(4):353-359 (1994).  |
|  | Alonso et al., "Systemic Hyperthermia in the Treatment of HIV-related Disseminated Malignancy. Long-Term Follow-Up of Patients Treated with High Flow or Low Flow Extracorporeal Perfusion Hyperthermia," approximate date 1992 (18 pages). |
|  | Alonso et al., "Systemic Hyperthermia in the Treatment of HIV-related Kaposi's Sarcoma. A Phase I Study," <u>Biomed &amp; Pharmacother</u> , 46(1):21-24 (1992).  |
|  | "Background - Summary of Findings, Site Visit Report-Clinical Use of Hyperthermia in AIDS," National Institute of Allergy and Infectious Diseases, September 4, 1990 (5 pages).   |
|  | "Extracorporeal Whole Body Hyperthermia," First Circle Medical, Inc., Doc. No. 1600002, 1999 (71 pages).  |
|  | February 25, 1994 Letter from the Department of Health and Human Services forwarding the "Full Report of the Site Visit Report - Clinical Use of Hyperthermia in AIDS" (24 pages, including cover letter).                                  |

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|  |  | Internal Medicine Specialists "From Mercury to Malaria to Penicillin: The History of the Treatment of Syphilis at the Mayo Clinic, 1916-1955" reprint of Journal of the American Academy of Dermatology, 1995; 32:255-261. |
|  |  | Logan et al., "Case Report, Total Body Hyperthermia in the Treatment of Kaposi's Sarcoma in an HIV Positive Patient," <u>Med. Oncol. &amp; Tumor Pharmacother</u> , 8(1):45-47 (1991).                                     |
|  |  | More, "Hyperthermia Finds Little Effect," <u>GMHC Treatment Issues</u> , Volume 9, Number 11, November 1995 (2 pages).   |
|  |  | Pontiggia et al., "Whole Body Hyperthermia Associated with Betacarotene Supplementation in Patients with AIDS," <u>Biomed &amp; Pharmacother</u> , 5:263-265 (1995).   |
|  |  | Pontiggia et al., "Whole-Body Hyperthermia Followed by Beta Carotene Supplementation in Patients with Acquired Immune Deficiency Syndrome (AIDS)," <u>Southern Medical Journal</u> , 88(10):S142 (1995).                   |
|  |  | PR NEWSWIRE "C. Everett Koop Joins First Circle Medical Board Former U.S. Surgeon General Supports Company's Effort to Develop a New Treatment for Patients with AIDS and Other Diseases" page 1, 1998.                    |
|  |  | Shecterle et al., "More on Hepatitis C", <u>The Scientist</u> , May 24, 1999.  |
|  |  |  |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.